

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

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) MDL No. 1456  
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THIS DOCUMENT RELATES TO  
01-CV-12257-PBS AND 01-CV-339

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) Civil Action No. 01-CV-12257 PBS  
)  
) Judge Patti B. Saris  
) Chief Magistrate Judge Marianne B.  
) Bowler

**BMS DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT  
OF THEIR MOTION FOR SUMMARY JUDGMENT AS TO CLASS 3**

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Defendants Bristol-Myers Squibb Company (“BMS”) and Oncology Therapeutics Network Corporation (“OTN”) (together “BMS”)<sup>1</sup> respectfully submit this memorandum of law, together with the Declaration of Denise M. Kaszuba, dated July 13, 2006 (“Kaszuba Decl.”), in support of their motion pursuant to Fed. R. Civ. P. 56(b) for summary judgment on all claims against them in the Third Amended Master Consolidated Complaint (“TAMCC”) asserted by or on behalf of Class 3, as certified by the Court in its Order dated January 30, 2006.

The Track 1 defendants have submitted a joint brief in support of their motion for summary judgment against Class 3. The joint brief identifies those “cross-cutting” issues fatal to Class 3’s case as to all Track 1 defendants. BMS joins in that brief.

BMS also incorporates by reference the memoranda and supporting declarations that it filed in connection with the motions for summary judgment with respect to Classes 1 and 2,<sup>2</sup> and, for the convenience of the Court, attaches to this brief some of the relevant documents and testimony already in the summary

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<sup>1</sup> OTN is a former wholly-owned subsidiary of BMS that distributes oncology products (including but not limited to those manufactured by BMS), primarily to office-based practices. Another former subsidiary of BMS, Apotheon Inc., is also named in the Third Amended Master Consolidated; however, it specialized in generic self-administered drugs that are not among the “Subject Drugs” listed in the Court’s January 30, 2006 Class Certification Order.

<sup>2</sup> The BMS Defendants’ Memorandum Of Law In Support Of Their Motion For Summary Judgment dated, March 15, 2006; The BMS Defendants’ Memorandum Of Law In Opposition To Plaintiffs Motion For Partial Summary Judgment, dated April 7, 2006; The BMS Defendants’ Reply Memorandum Of Law In Support Of Their Motion For Summary Judgment, dated April 28, 2006; the Affidavit of Denise M. Kaszuba, sworn to February 18, 2004; the Declaration of Zoltan Szabo, dated October 25, 2004; the Declaration of Steven M. Edwards, dated March 15, 2006; the Expert Declaration of Dr. Gregory K. Bell, dated March 15, 2006; and the Declaration of Lyndon M. Tretter dated, April 6, 2006. BMS also incorporates, and relies upon for the purposes of this motion, the Local Rule 56.1 Statement of Defendants Bristol-Myers Squibb Company and Oncology Therapeutics Network Corp., dated March 15, 2006.

judgment record that support its position. BMS's position, with respect to its own conduct, is as follows:

#### I. BMS'S LIST PRICES ARE NOT DECEPTIVE OR UNFAIR.

BMS does not report AWP's to industry publications; it reports wholesale list prices or "WLPs." (Tab 1.) For the drugs at issue in this case, those list prices are the prices that appear on invoices to wholesalers (Tab 2), and 86% of BMS's net revenue from 1993 to 2002 was generated from transactions within 5% of the list price. (Tab 3.)

During the period that BMS's products were protected by patents, BMS periodically increased its list prices for certain drugs. (Tab 2.)<sup>3</sup> It did not do so, however, unless it believed it could obtain sales at that new price. (*Id.*) During the period 1993 to 2002, for drugs at issue in this case protected by patents, 93.6% of BMS's net revenue was generated from transactions within 5% of the list price. (Tab 4.)

After a drug loses its patent protection, BMS generally does not raise its list price. (Tab 2.) Since BMS only reports changes in list price to industry publications, after a drug loses patent protection the list price (and hence the AWP) generally remains the same. (Kaszuba Decl. ¶¶ 3-4.)<sup>4</sup> Nevertheless, during the period 1993 to 2002, for drugs at issue in this case facing generic competition, 29%

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<sup>3</sup> Despite this, there were no list price increases for Vepesid, Taxol or Etopophos injectibles when each drug was on patent during the period 1993 to 2002.

<sup>4</sup> For this reason, where reimbursement is based on the median AWP, there can be no causal connection between the AWP for BMS's drug and any injury to the class because the AWP for BMS's drug – by definition – will never be the median.

of BMS's net revenue was generated from transactions within 5% of the list price.  
(Tab 4.)

Plaintiffs contend that BMS's list prices were deceptive or unfair because they were not adjusted to reflect discounts. A list price, by definition, does not reflect discounts. (Tabs 5-6.) Indeed, in the Medicare Modernization Act of 2003, Congress defined Wholesale Acquisition Cost or "WAC" (which is the functional equivalent of BMS's list price) as follows:

"(B) WHOLESALE ACQUISITION COST.--The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data."

42 U.S.C.A. 1395w-3a(c)(6)(B) (emphasis added).

In its summary judgment papers in connection with Classes 1 and 2, BMS cited numerous cases which demonstrate that there is no duty to disclose discounts. Alves v. Harvard Pilgrim Health Care, Inc., 204 F. Supp. 2d 198, 213-14 (D. Mass. 2002), aff'd, 316 F.2d 290 (2003); Bonilla v. Volvo Car Corp., 150 F.3d 62, 69-70 (1st Cir. 1998), cert. denied, 526 U.S. 1098 (1999); Langford v. Rite Aid of Alabama, Inc., 231 F.3d 1308, 1313-14 (11<sup>th</sup> Cir. 2000); Katzman v. Victoria's Secret Catalogue, 167 F.R.D. 649, 656 (S.D.N.Y. 1996), aff'd, 113 F.3d 1229 (2d Cir. 1997); Whitehall Co., Ltd. v. Barletta, 404 Mass. 497, 503, 536 N.E.2d 333, 337 (1989).

Plaintiffs did not distinguish those cases. Rather, in their reply brief on their motion for partial summary judgment against BMS, plaintiffs cited Matter

of Regina Corp., 61 F.T.C. 983, 1962 F.T.C. Lexis 92, at \*34-36 (Oct. 11, 1962) for the proposition that list prices must be “the usual and customary prices at which products are sold.” (Plaintiffs’ Reply Memorandum, dated April 28, 2006, at 3.) That case provides no support for plaintiffs and, if anything, the final result supports BMS.

First, Regina involved manufacturer suggested retail pricing advertised to consumers who made purchases at retail. The case is completely inapposite because (a) BMS does not suggest retail prices and (b) the publications are not addressed to or read by consumers, but rather prescription drug reimbursers: government regulators, health insurers, PBMs, benefits consultants and their corporate clients.

Second, even if Regina had some probative value, the decision cited by plaintiffs was subsequently modified by the FTC, see 65 F.T.C. 246 (1964), in light of then newly-adopted regulations providing that a list price “will not be deemed fictitious if it is the price at which substantial (that is, not isolated or insignificant) sales are made . . . .” 16 C.F.R. § 233.3. See also In Re Bulova Watch Co., 64 F.T.C. 1054 (1964) (dismissing complaint alleging deceptive list or “ticketed” prices of watch manufacturer where such list prices were not in “excess of the highest prices at which substantial sales were made in the area in which [the manufacturer] was doing business.”) Thus, BMS satisfies the Regina standard.

## II. SUBMITTING LIST PRICES TO PUBLICATIONS IS NOT DECEPTIVE OR UNFAIR.

Plaintiffs also contend that BMS engaged in unfair or deceptive practices by submitting its list prices to industry publications, knowing that they would apply a mark-up factor of 20%-25% to establish AWP's. BMS had no reason to believe that anyone was deceived by a mark-up factor of 20%-25%. That percentage mark-up is consistent with Hartman's 30% "expectation yardstick," and the government has conceded that "the spread between list price and AWP was known to the government in various ways, and assumed by the Medicare reimbursement system." (Tab 7.)

Furthermore, it is undisputed that BMS did not control the mark-up factor that the publications applied. (Tabs 8-10.) This is demonstrated by numerous documents that both sides proffered in the Classes 1 and 2 summary judgment motions:

- "AWP is outside the control of BMS."
- "AWP is not determined or set by BMS."
- "Pricing operations is NOT RESPONSIBLE for . . . establishing AWP's."
- "AWPs are established by Redbook."
- "BMS does not set AWP for its products."
- "AWP is not determined or set by BMS."
- Markups "are set wholly at the discretion of the data services."

(Tabs 11-16.)

Perhaps the most compelling proof is the fact that, beginning in 1999, BMS began to include in its communications with the publications an explicit statement that its list prices did not include discounts. (Tab 2, ¶ 5.) For example, one such communication states:

“Wholesale and Direct List Prices, including those for the products listed herein, may not reflect actual Bristol-Myers Squibb sale prices. Certain multisource products are always sold at lower special offer prices. All products may be subject to negotiated discounts, rebates and chargebacks.”

(Tab 17.) This had no impact on the way the publications reported AWP. (Tab 18.)<sup>5</sup>

First DataBank has stated: “Many customers are under the impression that the manufacturer sets the AWP. That is not true.” (Tab 19.) It has also made it clear that AWP is supposed to be a wholesaler’s list price, not the manufacturer’s list price. (Tab 20.) This is consistent with the definition of the Congressional Budget Office, an agency created by Congress to provide, among other things, objective nonpartisan analyses for members of Congress:

“The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider. It is not the actual price that wholesalers charge but serves more like a sticker price in the automobile industry. It was chosen as the reference price for this analysis because it is commonly used in pharmaceutical transactions.”

(Tab 21.)<sup>6</sup>

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<sup>5</sup> Nor has the public availability of average sales prices (“ASPs”) since 2005 changed the fact that the publications continue to publish AWP.

<sup>6</sup> It is also consistent with the way plaintiffs have defined AWP. (Tab 22, Response 1.)

BMS is not responsible for the actions of publishers (a) that it does not control, (b) that it has no reason to believe are deceptive or unfair, (c) that provide suggested wholesaler, not BMS, prices, and (d) that are directed to third-party payors with whom BMS has no business relationship. In re Cabletron Sys., Inc. 311 F.3d 11, 38 (1st Cir. 2002) (no control or endorsement); Ahern v. Scholz, 85 F.3d 774, 798 (1st Cir. 1996) (no reason to believe deceptive); L.B. Corp. v. Schweitzer-Mauduit Int'l Inc., 121 F. Supp. 2d 147, 152 (D. Mass. 2000) (no business relationship); John Boyd Co. v. Boston Gas Co., 775 F. Supp. 435, 440 (D. Mass. 1991) (no business relationship); Nei v. Boston Survey Consultants, Inc., 388 Mass. 320, 324-25, 446 N.E.2d. 681, 684 (1983) (no business relationship).

### III. ANSWERING PROVIDERS' QUESTIONS ABOUT SPREAD IS NEITHER WRONGFUL NOR THE CAUSE OF PLAINTIFFS' ALLEGED INJURY.

The undisputed documents and testimony with respect to BMS's sales and marketing practices for the Subject Drugs show that (1) while the drugs were on patent there were no spreads that, even on plaintiffs' theory of the case, give rise to liability (Tab 23); (2) after the drugs lost patent protection and became subject to generic competition, BMS did not change the list price and thus did not "manipulate" spread (Tab 2); (3) for customers who would otherwise switch to the generic, BMS's marketing department frequently approved price matching (Tab 24); and (4) BMS sales representatives did not actively promote BMS off-patent drugs and had no authority to negotiate price, but from time to time answered questions that medical providers had about AWP's on BMS drugs and/or the spread between the AWP's and the prevailing market price for the drugs. (Tab 25.)



Plaintiffs have suggested that BMS's conduct was contrary to the HHS/OIG "Compliance Program Guidance for Pharmaceutical Manufacturers," published in May 2003. Without agreeing that the OIG's Guidance is authoritative, BMS's conduct was entirely in accord with it and cannot be deemed deceptive or unfair under Massachusetts consumer protection laws. In any event, there is no causal connection between any of this activity and the alleged "overpayment" for BMS drugs by Class 3 members. See Hershenow v. Enterprise Rent-A-Car Co. of Boston, 840 N.E.2d 526, 528 (Mass. 2006). Neither BMS's willingness to meet generic competition on price nor any communication between a BMS representative and a medical provider could possibly have affected the reimbursement rate negotiated between the third-party payor and the provider.

#### IV. MASSACHUSETTS THIRD-PARTY PAYORS KNEW OF "MEGA-SPREADS" ON BMS MULTI-SOURCE DRUGS.

The Track 1 Defendants' joint expert, Eric M. Gaier, Ph.D, has submitted a Declaration dated July 14, 2006 in which he analyzes the prices at which the named Class 3 representative, Blue Cross Blue Shield of Massachusetts ("BCBSMA") and other large payors in the State acquired physician-administered drugs when buying for the purposes of their own HMOs. The data shows that BCBSMA and the other Massachusetts TPPs bought three BMS Subject Drugs, Vepesid, Blenoxane and Cytosan, during the years that those drugs were subject to generic competition at spreads ranging from 50% to 1260% (as spreads are calculated by plaintiffs' expert Dr. Hartman). (Tab 26.)

Obviously, since the Class 3 representative and other Class 3 members were buying BMS drugs at the complained-of “mega-spreads” for their own account, they cannot claim that they were unaware, let alone deceived, about the availability of such spreads in the marketplace.

Conclusion

For all the foregoing reasons, BMS respectfully requests that the Court enter summary judgment in favor of BMS on all claims asserted by Class 3.

Dated: Boston, Massachusetts  
July 14, 2006

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I, Lyndon Tretter, certify that on July 14, 2006 a true and correct copy of the forgoing document was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter

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Lyndon Tretter